Clinical Practice Model 2025 EXALT Model D

Clinical Practice Model Team

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🧭 Purpose & Strategic Objectives

This inaugural session launched a multi-phase effort to develop an expert-authored clinical implementation playbook for Boston Scientific's Exalt™ single-use duodenoscope. The goals were to:

Capture comprehensive real-world insights from KOLs

Structure clinical algorithms and procedural workflows

Address barriers to adoption across diverse care settings

Identify cost, training, and ergonomic considerations

Assign expert authorship to refine targeted content areas

The resulting document is envisioned as a turnkey, modular playbook that empowers clinicians across varied environments to adopt Exalt™ safely, efficiently, and effectively.

🔬 Key Clinical Insights

1. Infection Risk & Historical Context

Key Summary/Consensus:

- Duodenoscope related infections were a substantial concern in the 2010s and significantly impacted the safety of patients undergoing ERCP, which has intensified the focus on appropriate disinfecting and created a need for innovative device design.
- Duodenoscope-associated infections remain a latent but persistent threat, particularly in low-surveillance settings.

Highlights:

- 2014–15 CRE outbreaks catalyzed industry response
- Contamination still occurs despite disposable caps, elevators and enhanced reprocessing protocols like double HLD
- Risk particularly occurs at elevator mechanism and in instrument/sealed channels
- Reusable scope cleaning protocols vary widely by institution

Infection Risk & Historical Context (continued)

The first reported cases of duodenoscope-related infections occurred in Europe in 2012, and were shortly thereafter seen in the USA. Over 45 sites and all scope manufacturer types were involved. There were 250 reports of patient infections in 2015, which represented the peak of the outbreak. In 2018, there were 3 deaths of US patients related to duodenoscope related infections.

Cleaning protocols are notoriously complex and had not been previously validated clinically. Beginning in 2015, the FDA released the beginning of a series of communications and recommendations, including that the design of duodenoscopes contributes to user error and inadequate reprocessing. They ordered each duodenoscope manufacturer to conduct post market surveillance studies to understand contamination rates. As part of this analysis, it was found that users had difficulty understanding and properly executing cleaning and disinfecting, leading to steps being skipped. In 2019, the FDA recommended the transition to duodenoscopes with innovative designs that facilitate or eliminate contamination.

Additional enhanced disinfection strategies have been utilized, including Ethylene Oxide sterilization, Liquid Chemical Sterilant Processing system, microbiological culturing and quarantine, and repeat high-level disinfection. However, each strategy confers additional costs in terms of time and expense, and are unlikely to fully eliminate the risk of infection.

Additionally, there is evidence that harmful bacteria may be housed in areas other than the elevator itself, which suggests that endoscopes with disposable endcaps or scope tips may still harbor bacteria and convey risk.

Finally, establishing a definitive causal pathway between endoscope contamination and clinical infection is inherently challenging, as post-ERCP bacteremia and cholangitis are recognized procedural complications. The majority of documented cases of scope-transmitted infections have been identified through surveillance of antimicrobial-resistant organisms.

2. Procedural Algorithms & Use Case Tiers

Framework for Use of EXALT Model D: The current landscape of single use duodenoscopes continues to grow and develop. As one embarks on implementing EXALT into clinical practice it is extremely helpful to have clinical algorithm outlining for which cases your practice will use single use. The case-use scenario varies based on the details of the institution and practice.

The following is a useful algorithm for a large volume ERCP practice that may be a large referral-based community practice or a tertiary care academic center. This algorithm is based on a protocol previously published (Gromski M and Sherman S, GIE, 2022, PMID: 34487777). This algorithm focuses on two features of selecting single use duodenoscopes for high-risk cases which may a.) expose duodenoscope fleet to potentially resistant bacteria and b.) minimize exposure of patients with immune suppression to duodenoscopes which have a risk of contamination.

Tiered Use Algorithm (Large Volume Practice Model):

Tier 1: Use SUD

High risk infections (prior history of CRE, prior positive bile culture with resistant organism, prior biliary infections with antibiotic usage such as PSC or recurrent cholangitis)

Tier 2: Strongly consider SUD

Immune compromised patients (solid organ or bone marrow transplant patients, malignancy with chemotherapy, IBD/Rheumatoid arthritis/autoimmune disease or other on immune suppression).

Tier 3: Discretionary

Routine stone clearance, acute cholangitis, large caliber stent exchanges or removal

Special Use Cases for EXALT

Additionally, there is anecdotal evidence of specific scenarios which may engender improved performance with the use of the EXALT SUD

Duodenal stricture

Less resistance of tip of EXALT for passage through stenosis compared to disposable endcap of reusable duodenoscopes

EDGE procedures

Smoother passage of duodenoscope through LAMS in RYGB patient – without the resistance of the disposable cap of reusable duodenoscopes

EXALT + SPY synergy

Improved performance and stability of Spyglass single operator cholangioscopy through the channel and elevator of EXALT; cholangioscopy associated with elevated rates of bacteremia

After-hours procedures

Weekend/night ERCPs and last ERCP of day (to streamline/reduce staff time required to reprocess devices and to minimize delays in reprocessing reusable scopes)

Intraoperative procedures

Procedures performed during surgical interventions

In the above model, it is essential to have a discussion with partners who perform ERCP and with hospital administrators and nursing staff to achieve the following:

- Review the liabilities of reusable duodenoscopes (potential contamination post reprocessing, need for highly skilled reprocessing technician, need for high functioning infection prevention strategy to audit, need to monitor and enforce reprocessing program, potential for endcap dislodgement, scope performance issues related to sphincterotome alignment, image fogging and increased footprint of distal tip) and potential benefits.
- Work with manufacturer on exposure to SUD for all partners, acknowledging the learning curve (albeit short) and differences in adoption/preference based on years of practice.
- Agree upon usage criteria, acknowledging that the tiered approach above is a preferred policy, however the practicing endoscopist has final choice and responsibility for scope selection.
- Conclude that a well-thought-out algorithm for adoption of SUD into clinical practice is a part of an over-arching infection prevention and quality assurance program within the advanced endoscopy suite that can be highlighted to hospital administrators, patients and team members.

Low Volume Center Strategy

A second case use strategy is for the low volume regional center (that performs < 100 ERCPs per year). This may be an outreach facility for a larger referral center or a regional or rural center that is freestanding. In this case, there is a significant case use strategy for transitioning completely to SUD. This strategy has multiple potential benefits:

- Given relatively small ERCP procedure volumes, the shelf space of a few SUDs will not be over-whelming compared to a high-volume center.
- Allows for guarantee of an up to date and functional device
- The expectations and standards for duodenoscope reprocessing are uniform whether a high-volume center or low volume center. It is doubtful that a low volume center will be able to maintain scope processing technicians that can flawlessly perform every step of duodenoscope reprocessing. It is also an inordinate burden on the facility to be able to maintain the skills of reprocessing technicians, the AER and its associated materials, the auditing and feedback to technicians required, and the infection prevention strategies of a large volume center.
- It allows for centers which may have otherwise referred out ERCP cases due to shortages of personnel or knowledge or infection prevention expertise to now do ERCPs with SUDs.

Potential limitations to this second complete adoption strategy is the acceptance of SUDs among GI doctors who may infrequently perform ERCP and already feel unease about performing a complex and high-risk procedure. Citing experience in learning curve and literature on clinical outcomes in large series will be helpful.

Utilization Rates (KOL team)

Physician	Personal Use	Institutional Avg
Trevino	~85%	~50%
Pineda	~50–60%	~30%
Singla	~50%	15–20%
Gromski	~10%	~10%

3. Scope Reprocessing & Institutional Practices

Reusable duodenoscope reprocessing has been under increased scrutiny since the CDC alerted the FDA to potential risks of contamination with resistant organisms in reusable duodenoscopes in the Fall of 2013. In August of 2015, the FDA published supplemental measures to enhance duodenoscope reprocessing. These four supplemental measures are the following:

Culturing

Culturing of duodenoscopes post-reprocessing

Double HLD

Repeat high-level disinfection (double high-level disinfection [DHLD])

LCS

Liquid chemical sterilization (LCS)

EtO

Ethylene Oxide (EtO) sterilization

Since, the FDA has communicated guidance for centers in the US to adopt and use innovative duodenoscopes with disposable endcap components or fully disposable duodenoscopes (SUDs).

Scope Reprocessing & Institutional Practices (continued)

However, there has not been agreed upon strategy for reprocessing the current fleet of reusable duodenoscopes. Most centers across the US perform single or double high-level disinfection of modern duodenoscopes with disposable endcaps. A prior study has shown that post-reprocessing contamination rates of DHLD and LCS are equivalent (Gromski et al. GIE 2021. PMID: 32745532). Due to existing infrastructure and ease of use, most centers use high level disinfection over LCS. Prior randomized studies of older generation fixed endcap duodenoscopes comparing single vs. DHLD showed no significant improvement of using DHLD (Bartles et al. GIE 2018, PMID: 29476847; Snyder et al Gastroenterology 2017 PMID: 28711629). However, unpublished data from some centers using modern disposable endcap design duodenoscopes comparing surveillance culturing during an era of DHLD and a transition to single HLD found an increase in positive cultures after a change to single HLD. Many centers continue to perform DHLD for duodenoscopes due to its feasibility.

Also, it is a prudent infection prevention strategy at a center performing ERCP for reusable duodenoscopes to undergo periodic inspection of the working channel (either by internal staff or by the manufacturer) to evaluate for defects in the channel. Additionally, operators can also inspect the channel when performing cholangioscopy or pancreatoscopy. The duodenoscope is unique in the flexible GI endoscopy armamentarium in that it is not uncommon for endoscopists to perform endoscopic maneuvers through the working channel which may be injurious (e.g., pulling large-bore stents through the working channel, manipulating multiple devices which may periodically be inadvertently disengaged while passing through the working channel such as a stone retrieval basket or a cytology brush).

It should be widely recognized that the complexity of reprocessing a duodenoscope is likely the highest of all flexible endoscopes and the potential risk of an improperly reprocessed duodenoscope is among the highest in the healthcare setting. Endoscopy reprocessing technicians are too often underpaid and underappreciated given these challenges. There should be training programs and advancement ladders for the purpose of career building and retention in this field.

Last, due to the transition to reusable duodenoscopes with disposable endcaps and regulatory hurdles, many niche duodenoscopes are no longer commercially available or supported, such as a smaller caliber duodenoscope or a dedicated pediatric duodenoscope. These scopes are very important for a small number of cases, and in the absence of these scopes, some cases will not be able to be performed endoscopically and will need to be referred for IR or surgical intervention. If such a case were to arrive (e.g., young pediatric patients, significantly narrowed anatomy secondary to prior surgery or in situ stricturing disease), one can consider referral to a center which maintains legacy fixed endcap duodenoscopes of this caliber. In centers utilizing legacy fixed endcap duodenoscopes, we recommend an approved institutional policy regarding SUD use criteria and utilization of an enhanced duodenoscope reprocessing strategy involving DHLD, culturing or liquid chemical/EtO sterilization.

4. Literature Interpretation & Impact

Key Studies Cited:

- Slivka et al: Experienced endoscopists had numerically higher crossover rates—suggesting greater flexibility in newer users
- Bruno et al: International multicenter trials: Non-inferiority of SUD across ASGE 3–4 grades

Insights:

- Hands-on experience influenced adoption more than literature alone
- Exalt shown to be viable across the full procedural spectrum
- No patient billing identified in any represented institution

Key Summary: Ample evidence suggests that the technical success rates of single-use duodenoscopes is similar to that of reusable devices.

Clinical Utility of Single-Use Duodenoscopes

Authors	Year	Study Type	Key Take Home Points
Muthusamy VR et al	2020	Multicenter case-series	First study reviewing the possibility of completing moderately complex (majority ASGE 2 and 3) ERCP's with a SUD, demonstrating that expert endoscopists were successful in vast majority (58/60) of patients undergoing ERCP.
Napoleon B et al	2021	Multicenter case series	60 patients were enrolled, and 57 of these were completed successfully with a SUD. The three failures were also unsuccessful with a reusable duodenoscope.
Slivka A et al	2021	Multicenter case-series	High technical success rates by expert (>2000 lifetime ERCP) and non-expert endoscopists. Lower cross-over rate amongst non-expert endoscopists (though not statistically significant) may suggest more learning flexibility in this group.
Bang JY et al	2021	Randomized controlled trial	Technical performance and safety profile similar between single-use (N=48) and reusable (N=50) groups. Majority low-complexity

5. Training, Ergonomics, and Technical Learning Curve

Learning Curve Estimates:

- ~10 consecutive cases recommended for proficiency
- New trainees may adapt faster than senior users with entrenched muscle memory
- Fellows reported comfort when trained from the outset on both Exalt and reusable

Tips & Tricks:

- Start with mild manipulation and maintain active neutralization of control knobs
- Clean lenses aggressively (e.g., Fred™ cleaning) to maintain visibility
- Ergonomic feedback: lighter design reduces strain
- Imaging: Visual horizon can be different due to more proximal view

General Overview of EXALT Usage

The design of the EXALT D duodenoscope is based on the design of the reusable duodenoscope; therefore, once the experienced physician is committed to using the single use duodenoscope, he or she has very little difficulty learning and adapting to the technology.

For the new therapeutic endoscopy fellow, overall, the learning curve does not appear to be different from the learning curve expected for a reusable duodenoscope.

The EXALT duodenoscope is lighter than the reusable duodenoscope; this could reduce muscular and skeletal stress to the provider.

The shaft and tip of the scope are slightly stiffer; this affords stability of the scope in the duodenum once in position and pushability of instruments through the channel of the scope into the biliary and pancreatic ducts. This could translate into enhancing clinical success and reduced procedure times in terms reducing body stress and injuries.

Device Preparation and Disposal

Video 1: Demonstration of taking EXALT out of the box and preparing it for use (and also demonstrating disposal into recycling bin from recycling service)

Unboxing

The scope comes in a hard box and in soft packaging. Unbox the scope and place it on a flat surface. Tear the soft packaging carefully and remove the scope from the soft back holder. The buttons come in a small hard plastic box.

Optics Test

Test the optics of the camera and use a lens cleanser like Fred anti-fog solution. This enhances the visibility during the procedure. (If the scope visibility worsens before cannulation, it is advisable to remove the scope and re-apply the Fred solution).

Function Check

Once the buttons are connected make sure to check all aspects of scope function including the wheel deflection and elevator engagement and sturdiness. Make sure to lock and unlock the wheels and test the suction and air. If there are issues regarding air/water circuit (leakage), may consider adding lubricant to the stems of the buttons.

Disposal

For scope disposal, once the procedure is complete, turn the processor off, unplug the air and water connections, and unplug the scope from the unit. Wipe the shaft of the scope and fold it in half, then place it in the recycling bin. The recycling bin can hold several scopes.

Scope Insertion and Cannulation

Video 2: Demonstrates scope insertion, passage through the esophagus, advancement to the ampulla, positioning tips prior to cannulation attempt, cannulation, and tips to avoid adverse events.

Initial Considerations

Due to the light weight and the rigidity of the EXALT D scope, the force needed to advance the scope and its maneuverability may be different compared to the reusable duodenoscopes.

Esophageal Intubation

For safe intubation of the esophagus, lube the back of the deflecting distal end of the scope, start in neutral position with the tip of the scope straight. The flexing tip of the scope should be oriented towards the feet of the patient.

Always keep complete visualization of the lumen and use small movements. Avoid excessive pushing against a red-out image. When excessive resistance is encountered, retract the scope to visualize the lumen and clarify the anatomy. Sometimes, if not previously done, an EGD with dilation of the esophagus or duodenum may be needed for safe esophageal intubation and for traversing the proximal duodenum, similar to standard duodenoscopes.

Technique Tips

Overall, only a slight tip deflection combined with careful wrist movements is required to intubate the oropharynx. Do not overflex the scope in the mouth which will prevent the passage of the scope into the oropharynx.

Once the upper esophageal sphincter is intubated keep insufflating the lumen to maintain its visualization. Make sure to straighten up the scope in the esophagus and always pay attention to the level of resistance (do not push against resistance).

Once at the gastroesophageal junction, make sure to visualize the GEJ to exclude high-grade strictures. Visualizing the gastric lumen prior to gastric passage can avoid placing excessive lateral pressure on a hernia sac which can cause perforation.

Scope Insertion and Cannulation (continued)

Gastric and Duodenal Navigation

Avoid over insufflating the gastric cavity but keep visualization of the lumen. Suction liquid material to enhance visualization of the pylorus.

Adjust the position of your body and left hand to keep the lumen in view. These changes are based on the patients' position i.e.: supine, left lateral or prone.

Keep the pylorus in view before advancing into the duodenum, straightening the tip of the scope as the scope is pushed into the duodenal bulb.

Once in the duodenal bulb, stop, pull back, clean and insufflate. To advance into the second portion get to the apex, then "little wheel away" and "big wheel towards you", all in one motion along with a slight pulling of the scope which will safely advance the tip of the scope into the second portion. Fluoroscopy should be used to aid in understanding the scope positioning in difficult duodenal intubation.

Cannulation and Withdrawal

For biliary cannulation, position the scope slightly under the ampulla. The technique for biliary cannulation is the same as with the reusable duodenoscope. Aim from "right low to left high" towards the eleven o'clock position. Due to a slight difference in the angle of the camera with the EXALT D duodenoscope, if the ampulla is slightly outside of the range of the camera, position the scope in a semi-long or long position with the aim of visualizing the ampulla.

Prior to removing the scope, unlock the wheels and bring the tip of the scope to a neutral position. Keep the principles of visualizing the lumen, decompressing, withdrawing gradually

Be cognizant to recognize unusual resistance which needs to be explored rather than using excessive force.

ERCP Maneuvers and Device/Accessory Utilization Tips

Video 3: Clinical video demonstrating utility of the device.

Video 4: Cholangioscopy and Pancreas Cannulation

Versatility

The EXALT D duodenoscope can be used for the entire spectrum of diagnostic and therapeutic procedures in the pancreato-biliary system.

Cannulation Success

The rate of successful cannulation of both the biliary and pancreatic ductal systems is comparable to that achieved with reusable duodenoscopes.

Stability Benefits

The relative rigidity of the shaft of the scope affords excellent stability once positioned in the second portion of the duodenum. This stability decreases the potential of losing positioning of the guidewire due to loss of scope position (especially important in the supine position).

Procedural Advantages

Improved stability also increases the reliability of utilizing 2 wires and aids in pushing stiff diagnostic and therapeutic equipment into the biliary and pancreatic system.

Stone Management

Similar benefits are observed when placing plastic and uncovered metal stents into the right and left intrahepatic biliary system and when removing large bile duct and pancreatic duct stones.

Advanced Applications with EXALT

Cholangioscopy

The use of spyglass for cholangioscopy can be reliably performed with the EXALT D duodenoscope due to its stability once in the duodenum by affording intubation of all the biliary systems without losing its position. This helps in the diagnosis, and mapping of the biliary system for planning surgical intervention as well as for treatment of large stones with electrohydraulic lithotripsy.

Instrument Compatibility

The channel is large enough to accommodate the passage of all currently used disposable equipment and for the removal of plastic and FCMS without having to lose position by removing the scope.

Navigational Advantages

Its tip design and sturdiness allow the device to navigate narrowed lumens and traverse LAMS stents with improved ease, potentially reducing stent dislodgements and device related lacerations/perforations.

6. Adoption Barriers & Institutional Strategy

Barriers:

Cost sensitivity

A key concern about disposables is cost. In reviewing costs related to various sources evaluation must include capital purchase, staff time (including reprocessing, inventory, continued surveillance), repair and replacement cycles and infection complications. In low- to mid-volume centers, single-use scopes have been shown to be potentially cost-neutral or even cost-saving.

Lack of infection data in low-volume centers

This absence of data = false sense of safety.

Resistance to mandates from administration

In meeting with administrative decision makers, can focus on expanding education regarding above key clinical episodes of infection and indication to decrease contamination risk. Should also focus on other benefits including ergonomic, specialty scope and potential for operational efficiencies.

Skepticism among senior endoscopists

Utilizing new devices can be intimidating, especially in setting of knowledge and comfortability with current device. Concerns about performance and image quality have been addressed in multiple prospective trials. Learning curve appears short.

Adoption Tips

Start with pilot programs

Start with pilot programs or non-mandated algorithms, while giving an outline for reference on what patient population can benefit from use of single use duodenoscopes. Want to present a collaborative initiative on quality of ERCP in regards to infection control and safety.

Use real-world data

Use real-world data, patient testimonials, and infection trends

Encourage autonomy with guidance

Encourage autonomy while offering structured guidance. Invite physicians to be involved in Hands-on training. Review and offer real-world metrics from peers. When reviewing and selecting cases, aim for initial use in lower-complexity cases over a short time interval. Familiarity typically occurs within 5-10 cases, ideally performed within a short time span to build on prior experience.

Involve all stakeholders

Involve nursing and billing teams early and conduct a hands-on in-service to afford comfort to staff.

Highlight efficiency gains

Utilize to improve efficiency and reduce staff utilization for after-hours procedures when reprocessing is unavailable or limited reprocessing capabilities

7. Reimbursement, ROI, and Operational Efficiency

Summary:

- The move to single-use duodenoscopes represents a strategic investment in patient safety, infection control, and operational efficiency.
- Adopting single-use duodenoscopes can offer significant benefits in reimbursement alignment, infection prevention, and operational efficiency.

Cost Considerations:

Initial pass-through code sunset

Previous CMS new device pass through code was a bridge, now expired July 2023. There is a currently active C-code with revenue code.

1. Active C-Code: C1748
2. Revenue Code 278 (Implant)

If available, a consider periodic audit of charge and recovery data to monitor CMS and commercial payor reimbursement.

Reimbursement Landscape

General ERCP reimbursement increased (CMS) and most private insurers reimburse above device cost. There have not been any known instances of patients being billed for Exalt.

Capital Investment Considerations

In lieu of a large capital investment for increasing fleet number and for the need for reprocessing equipment at new sites of service, EXALT can be utilized to reduce the need for reusable duodenoscopes and avoid the purchase of new endoscopic reprocessing equipment/implementation of supplemental duodenoscope reprocessing, especially in low to mid volume centers.

Infection Cost Avoidance

EXALT eliminates expenses related to reprocessing, maintenance, and potential infection-related treatments. Infections associated with reusable duodenoscopes can be costly. Using single use duodenoscopes can mitigate these risks and associated costs.

Efficiency Gains

Faster Room Turnover

No reprocessing means faster room turnover—Allows technicians to quickly clean room and process for new procedure, therefore increasing procedural volume capability. Staff can be reallocated to other clinical and patient care duties when not reprocessing scope.

Consistent Availability

Avoids delays due to broken/contaminated reusable duodenoscopes—If reusable scope fleet is reduced due to damage or contamination, this may slow turnover for up to an hour while waiting for a fully reprocessed scope to be available for the next case. With single use duodenoscopes, there is consistent availability, eliminating downtime due to maintenance or contamination. Therefore, this allows optimizing procedure scheduling and throughput.

After-Hours Benefits

Lower burden on staff, especially after-hours—Reprocessing times for reusable scopes can take up to 60 minutes, keeping staff there longer, which will increase time spent and labor costs. Primarily can affect staff after hours, evening and weekend cases. Use of a SUD can streamline these after hour procedures and reduce overall labor expenses.

8. Future Needs: Innovation, Data, Sustainability

Innovation Requests:

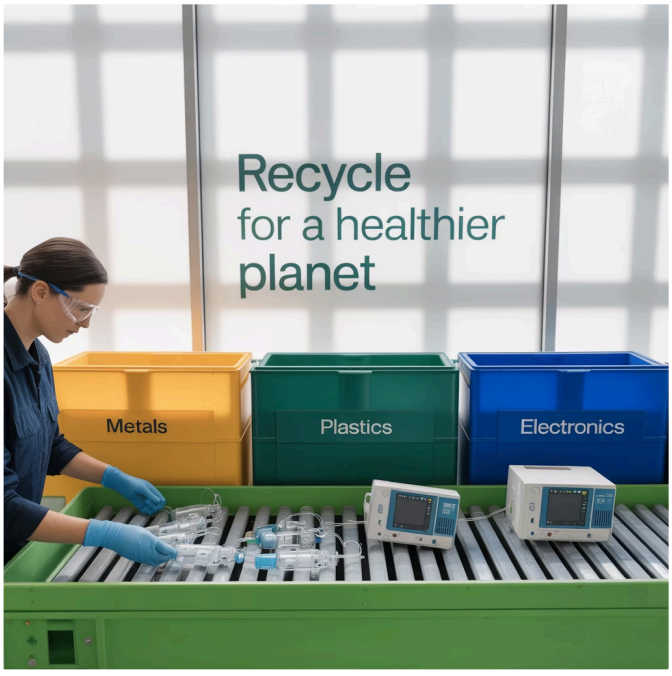
- Pediatric-caliber scopes
- Forward viewing options
- Altered-anatomy variants
- Ergonomic customization (e.g., for hand size)
- Incorporation of AI

Data Needs:

- Better cost transparency from payors and institutions
- Real-world studies in low-volume settings
- More robust environmental impact metrics

Environmental Considerations:

- 90%+ of scope components can be recycled
- Largest carbon footprint comes from scope production, not waste
- Further transparency needed on recycling supply chain



Future Innovations

Future modifications/benefits (small caliber scope, extra-long device, forward and side viewing devices, adjustable handles for supine ERCP).

Dual-View Systems

Possible future innovations in the design of duodenoscopes could include forward and side viewing camera systems that can be toggled. This system would allow for diagnostic and therapeutic interventions in the lumen of the upper GI tract with the duodenoscope itself, rather than using two scopes. Examples of this could include visualization and potentially even dilation of an esophageal/duodenal stricture prior to passage of the device, sampling and removing lesions, and treating active bleeding or mucosal lacerations/perforations.

Larger Channel Options

A duodenoscope with a larger diameter channel could allow for the passage of two instruments at the same time. Possibly this could aid in cannulation in difficult ampullary positions, redundant folds that cover the ampulla or an ampulla inside a deep but narrow opening diverticulum. Also, this could facilitate the passage of larger instruments into the biliary and pancreatic system. For example, a therapeutic spyglass cholangioscope with a larger channel could be developed.

Small Caliber Scopes

Small caliber scopes could be crucial for the performance of ERCP in patients with narrow duodenal lumens and aid in the passage of the scope through a previously placed AXIOS stent.

Conserving the size of the channel and the quality of the optics in small caliber ERCP scopes, although technically challenging, could be an extra added benefit in therapeutic ERCP.

Specialized Variants

Extra-long duodenoscopes could facilitate the performance of ERCP in patients with altered anatomy such as pancreaticoduodenectomy and RYGB.

Smaller handles for female users and adjustable/rotatable handles for difficult ERCP positions (supine) could improve scope ergonomics.

Data Needs

- Further data needs to be acquired both in tertiary care and in community centers regarding the reporting of infections associated with the use of reusable duodenoscopes and the cost reduction by avoiding clinical infections, morbidity and mortality by using the EXALT duodenoscope.

- Cost analyses regarding how more widespread adoption of the EXALT duodenoscope could bring an economy of scale to reduce the cost of making the device and how this could affect future pricing of the technology.

- Data regarding the clinical performance of the EXALT duodenoscopes among lower volume endoscopists, benefits with regard to operational efficiency, and overall cost of incorporation are needed in community/smaller hospital settings.

- The environmental impact of the production, distribution and disposal of these devices needs ongoing evaluation with continued efforts to reduce the carbon footprint associated with their utilization.

- Finally, further effort should be made to assess the utility of SUD in other countries/health systems with collection of data regarding clinical outcomes and economic feasibility.

🌍 Strategic Implications

Exalt™ is positioned not just as a procedural device but a systems-level infection control and operational efficiency solution. While broad adoption is still evolving, the panel strongly supports its role in:

Enhanced Safety

Enhancing safety in immunocompromised populations

Reduced Liability

Reducing institutional liability

Operational Efficiency

Supporting efficient ERCP services, especially at night/weekend

Specialty Applications

Filling the gap left by shrinking specialty reusable scope portfolios